

## **DETAILED ACTION**

### ***Request For Continued Examination***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/21/2007 has been entered.

### ***Claims Under Examination***

Claims 1, 3, 4, and 5 are under examination. Claim 2 is cancelled.

### ***Information Disclosure Statement***

The information disclosure statement filed 10/14/2003 has been considered in full.

### ***Priority***

This applicant has been granted the benefit of priority to Provisional Application 60/396,908, filed July 17, 2002.

### ***Withdrawn Rejections***

The rejection of claims 1-5 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn in view of applicant's amendment of the claims, filed 12/21/2007.

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The rejection of claims 1-5 under 35 U.S.C. 112, first paragraph, for lack of written description is withdrawn in view of applicant's amendment of the claims, filed 12/21/2007.

The rejection of claims 1-5 under 35 U.S.C. 103(a) as being made obvious by Salamov et al. (Bioinformatics, 1998, Vol. 1, No. 5, p.384-390), in view of Zhang et al. (Proc. Natl. Acad. Sci., 1997, Vol. 94, p.565-568, as filed in the IDS), is withdrawn in view of applicant's arguments and amendment of the claims, filed 12/21/2007.

***New Matter***

Claims 1, 3, 4, and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection. Claim 1 has been amended to recite a step of "transmitting codon location to a user of the computer system." In the response filed 12/21/2007, applicant does not point to support for the newly recited limitations. The Examiner has not found support for these limitations in the specification, and these limitations are not present within the scope of the original claims as filed. As the newly recited limitations are not supported by the originally filed claims or disclosure, the claims are rejected for reciting new matter. This rejection is necessitated by amendment.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3, 4, and 5 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. These claims are rejected for the following reasons.

Claims 1, 3, 4, and 5 are drawn to methods for finding translation initiation codons in a nucleotide sequence. For a method to be statutory, it must provide: (1) a practical application by physical transformation (i.e. reduction of an article to a different state or thing), or (2) a practical application that produces a concrete, tangible, and useful result [State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998)], [AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999))]. As noted in State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), the statutory category of the claimed subject matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result. The question of whether a claim encompasses statutory subject matter should not focus on which of the four categories of subject matter a claim is directed to a process, machine, manufacture, or composition of matter--but rather on the essential characteristics of the subject matter, in particular, its practical utility.

In the instant case, the claimed methods do not result in a physical transformation of matter. Where a claimed method does not result in a physical transformation of matter, it may be statutory where it recites a result that is concrete (i.e. reproducible), tangible (i.e. communicated to a user), and useful result (i.e. a specific and substantial). Claim 1 now recites a step for "transmitting" information to a user of the computer system. This is not a tangible result because the transmission of data does not communicate a result in a user readable format. Therefore the claimed method does not recite a practical application of a 35 U.S.C. 101 Judicial exception and is not statutory.

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This rejection could be overcome by amendment of the claims to recite that a result of the process is outputted to a display, or to a user, or in a graphical format, or in a user readable format, or by including a result that is a physical transformation. The applicants are cautioned against introduction of new matter in an amendment. For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter in the MPEP 2106, Section IV. The applicants are cautioned against introduction of new matter in an amendment.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 4, and 5 are rejected under 35 U.S.C. 103(a) as being made obvious by Salamov et al. (Bioinformatics, 1998, Vol. 1, No. 5, p.384-390), in view of Zhang et al. (Proc. Natl. Acad. Sci., 1997,

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Vol. 94, p.565-568, as filed in the IDS), and in view of Cai et al. (Bioinformatics, 2000, Vol. 16, No. 2, p.152-158; as filed in the IDS).

Salamov et al. teach a method for finding translation initiation codons in a nucleotide sequence [Abstract]. More specifically, Salamov et al. teach the following aspects of the instantly claimed invention:

- Obtaining a “positive” data set comprising real ATG start codons and other false ATG nucleotides (i.e. pseudoinitiator codons) and a “negative” (i.e. control) data set that includes regions after the initiator codon [p.386, Col. 2, ¶ 3]
- Defining six characteristics (i.e. features) of initiator codons [p.386, Col. 2, ¶ 5 – p.387, Col. 2, ¶ 2], which include scoring functions and parameters used to analyze sequence position data around each ATG region [p.387, Section (1)], and positional weight scoring functions to quantify resemblance of ATG triplets to initiator codons [p.387, Col. 1, Section (5)], as in claim 1, step b).
- Using Linear Discriminant Analysis (LDA) to determine the probability that each ATG in the positive data set (i.e. first data set) is an initiator codon based on determining the top scoring ATGs from each sequence [Fig. 2(a)], as in claim 1, step c).
- Using LDA to determine the probability that each ATG lying above a threshold in the negative data set (i.e. second data set) is a true initiator codon [Fig. 2(b)], as in claim 1, step d) and e)].
- Combinations of features comprising frequency of codon initiators, frequency of coding and non-coding regions (i.e. codon usage) around each ATG from –14 to +5, and in-frame hexanucleotide composition (i.e. in frame hexamer composition) [p.388, Sections (1) and (2)], as in claim 1 and Table 1.

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- Scoring functions directed to upstream ATG scores (i.e. Upstream Codon Score) [p.388, Section (5)], and measure of accuracy scores (i.e. Score) [p.388, Col. 2], as in claim 3 (Table 2) and outputting results [Fig. 2].

Salamov et al. do not specifically teach the use of “Bayes Network Construction” in generating a quadratic discriminant function, as in claim 1 (step c).

Zhang et al. teaches the identification of protein coding regions in nucleotide sequences using quadratic discriminant analysis (QDA) and Bayes Theorem [Abstract]. In particular, Zhang et al. teaches data analysis of first and second data sets (i.e. exons and pseudo-exons) using a combination of nine feature variables (e.g.  $x_1, x_2, \dots, x_9$ ), calculation of performance measures using Bayes theorem [p.566, Col. 2, ¶ 1], and correlations coefficients greater than 0.8 [Table 2 and 3], as in claims 1, 4, and 5. Zhang et al. do not specifically teach feature variable names as recited in claims 4 and 5 (Table 3). However, Zhang et al. clearly teaches feature variables for frame-specificity (e.g.  $x_7$ ), frequency (e.g.  $x_2$ ) over a plurality of different windows, and codons (e.g.  $x_1$ ), as well as variables for data correlation (CC), as in claims 4 and 5. It is noted that no “feature variables”, equations, or functions are recited in the claims that would serve to illustrate in what way “any combination of feature variables provided in Table 3 wherein the combination comprises one feature variable from each of any two feature variable classes,” as recited in claims 4 and 5, differentiates the claimed invention from the teachings of Zhang.

Cai teaches the application of Bayes Networks in the form of trees to the problem of modeling splice junctions in DNA sequences to improve the performance of gene-finding systems [Abstract and p.152, Col. 2]. Cai teaches provides guidance on the construction of probabilistic tree models [p.153, Col. 2], provides a generic function and variables for scoring any particular sequence in order to compute the probability that particular sequences are generated by a model [p.154], and using trained models to classify unknown sequences [p.155, Col. 1].

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Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the method of finding translation initiation codons as taught by Salamov et al. using the Bayes Theorem technique of Zhang et al. or the Bayes Network method of Cai, since both Bayes Theorem and Bayes Networks are probabilistic methods used by gene-finding systems, as suggested by Zhang [Abstract] and Cai [Abstract]. One of ordinary skill in the art would have been motivated to combine the above teachings in order to use a well known technique for improving data classification in predictive models as suggested by Zhang et al. [p.565, Col. 2], or in order to improve the performance of gene-finding method of Salamov et al, as suggested by Cai [Abstract and p.152, Col. 2], resulting in the practice of the instant claimed invention with a reasonable expectation of success.

### ***Response to Arguments***

Applicant's arguments filed 12/21/2007 that Salamov and Zhang do not teach the generation of a quadratic discriminant function using a combination of feature variables and Bayes Network construction as required by amended claim 1 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground of rejection is made in view of applicant's amendment of the claims to require Bayes Network construction, as applied above.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**/Pablo S. Whaley/**

Patent Examiner

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/John S. Brusca/

Primary Examiner, Art Unit 1631